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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,974	12/26/2001	Kouichirou Hirata	2001_1888A	8006
513	7590	05/26/2004	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/018,974

Applicant(s)

HIRATA ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-3,5-8,10-12 and 14-18.Claim(s) withdrawn from consideration: None.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claims 1-3, 5-8, 10-12, 14, 17-18 is maintained for the reasons already of record. The rejection was on the it would have been prima facie obvious at the time of applicants' invention to modify the polyclonal anti-S.sobrinus antibody of Babaahmady et al., since no more than routine skill would have been required to improve upon the antibody's binding specificity for anti-S.sobrinus antibody as compared to its specificity for S.mutans. Contrary to applicants assertions, one would have a reasonable expectation of success because Babaahmady et al., already teach the desire to have the antibody distinguish between S.sobrinus and S.mutans and only an expected increase in binding specificity would be obtained, since the prior art clearly teaches the desire to have more specific antibodies and the art teaches a variety of ways to make an antibody more specific for the particular antigen. Applicants' assert that the individual references fail to teach each and every element of the claims, however in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants assert that because Cabilly recites a variety of ways to improve antibody selectivity Cabilly is not enabled to make such antibodies. However, Cabilly does not have to teach specific characteristics when the prior art, Babaahmady already teach the specific desired characteristics, the desire to detect S. sobrinus and S. mutans, and assays to determine antibody sensitivity. No more than routine skill would be required to determine which antibody has the desired specificity. Therefore applicants arguments are not persuasive. Moreover, the claims are not limited to applicants method of making the claimed antibody, rather the claims are drawn to antibodies with specific characteristics and the prior art antibodies meet those claimed characteristics. The claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The rejection of claims 15 and 16 is also maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants invention to modify the immunochromatographic strip of Sommer to include the polyclonal anti-S.sobrinus antibody of Babaahmady et al., and Cabilly et al., since no more than routine skill would have been required to exchange the antibody and use one which preferentially detects S.sobrinus. One would have a reasonable expectation of success since one of ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent change. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, only the expected labeling effect would have been obtained, since the prior art clearly teaches the detection of S.sobrinus and relating it to the determination of the bacteria's presence. Therefore a skilled artisan would have had a reasonable expectation of success in switching the antibodies. The use of alternative and functionally equivalent antibodies would have been desirable to those of ordinary skill in the art based on the availability and known specificity of the polyclonal antibody.